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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,588	12/03/2004	Eishun Tsuchida	0020-5327PUS1	9917
2292	7590	02/01/2006	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			SHIRALI, SHYAM S	
			ART UNIT	PAPER NUMBER
			1654	
DATE MAILED: 02/01/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/516,588		TSUCHIDA ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Shyam Shirali		1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/04, 03/05</u>  | 6) <input type="checkbox"/> Other: ____.                                    |

### **DETAILED ACTION**

1. Applicant's election with traverse of 1-4 in its response to the Election of species requirement

of 08/15/2005 is acknowledged. The traverse is based on the grounds that search and examination of one species will encompass the other species so that no undue burden is placed on the examiner.

Alternatively, upon allowance of a generic claim the examiner is requested to consider claims of additional species that include all of the limitations of the allowed generic claim as provided by 37 C.F.R. 1.141.

Applicants argument is not found persuasive because, as Examiner explained in the election of species requirement of 08/15/2005 a separate search is required for each species. The applicant traversed on the grounds that the species are not patentably distinct, applicant did not submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case.

Claims 1-3 reads on the elected species, claim 4 is withdrawn from the consideration pursuant to 37 C.R.F.1.142. As being drawn to a nonelected invention. Thus, claims 1-3 will be examined on the merit.

The restriction requirement is still deemed proper and is therefore made final.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 (4 is withdrawn) are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuchida et al., (Bioconjugate chem., 1999, 10, 797-802), and Tsuchida et al. (Bioconjugate chem., 2000, 11, 46-50).

Tsuchida et al., (Bioconjugate chem., 1999, 10, 797-802) teaches that substituted amido phenylporphyrinatoiron(II)s (FePs) are incorporated in hydrophobic cavities of recombinant human serum albumin (rHSA), providing a synthetic O<sub>2</sub> carrier hemoprotein under physiological conditions. ( col.3, line 65).

Tsuchida et.al. (Bioconjugate Chem., 1999, 10, 797-802) does not teach the finding of cyclic amido phenylporphyrinatoiron (II).

Tsuchida et al. (Bioconjugate chem., 2000, 11, 46-50) teaches that amidophenylporphyrinatoiron(II) analogs related to the substituted porphyrins in combination with albumin show a good activity in the anesthetized rats (page 47, results and discussion).

It would be been obvious to make the substituted cyclic 1-methyl cyclohexanyl amido phenylporphyrinatoiron (II) because the minor structural changes between this compound and the compounds made by Tsuchida (Bioconjugate chem., 2000, 11, 46-50) would not be

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expected to alter the O<sub>2</sub> binding characteristics of the molecules.

Tsuchida et. al.(Biocojugate Chem.) showed that human serum albumin (HAS) incorporating synthetic hemes (FeP)s is an artificial hemaprotein (HAS-FeP) which is able to reversibly bind and release dioxygen under physiological conditions. The physiological response to exchange transfusion with HAS and (FeP)s into the rats has been discussed. He also discusses and determined the half life time of deoxygenated HAS-FeP.

It would have been obvious to one of ordinary skill in the art that the similar molecule with Formula I in claims with R=methyl cyclohexanol substitution would be motivated to combine the teachings of experimentation to modify the phenylporphinatoiron(II) and use albumin clathrate as a dispersion.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shyam Shirali whose telephone number is (571)-272-5547. The examiner can normally be reached on 8.00am to 4.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr.Bruce Campell can be reached on (571) 272- 0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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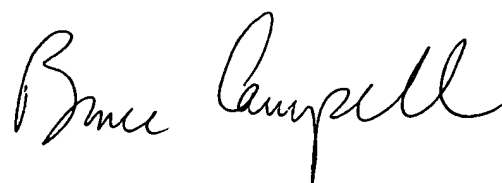
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Shyam Shirali

Patent Examiner

Office : Rem 3D10

Ph: (571)272-5547

A handwritten signature in black ink, reading "Bruce Campell". The signature is written in a cursive style with a large, stylized "B" and "C".

**BRUCE R. CAMPPELL, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600**